UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK VICINAGE

MARGARITA SANTIAGO AND HECTOR SANTIAGO, w/h	:	CIVIL ACTION
Plaintiffs,	:	No.
vs.	:	Honorable , U.S.D.J. Honorable , U.S.M.J.
BOSTON SCIENTIFIC CORPORATION,	:	**CIVIL ACTION COMPLAINT** **JURY TRIAL DEMANDED**
Defendant.	:	

COMPLAINT

Plaintiffs, Margarita Santiago and Hector Santiago, w/h, by and through their counsel, Messa & Associates, P.C. file this Complaint against Defendant, Boston Scientific Corporation, averring as follows:

Parties

1. Plaintiff Margarita Santiago is a resident of the State of New Jersey who resides at 69 Broadway Elizabeth, New Jersey 07206.

2. Plaintiff Hector Santiago is a resident of the State of New Jersey who resides at 69 Broadway Elizabeth, New Jersey 07206.

3. At all times material hereto, Plaintiffs Margarita Santiago and Hector Santiago were and still are legally married.

4. Defendant Boston Scientific Corporation is a Delaware corporation with its corporate headquarters in Massachusetts. All acts and omissions of Boston Scientific as described herein

were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

Jurisdiction and Venue

5. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendant(s) and the amount in controversy exceeds $75,000.

6. Defendant has significant contacts with the federal judicial district identified in the Short Form Complaint such that they are subject to the personal jurisdiction of the court in said district.

7. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in the Short Form Complaint. Pursuant to 28 U.S.C. § 1391(a), venue is proper in said district.

The Pelvic Mesh Product

8. Defendant Boston Scientific's Pelvic Mesh Product (the "Product") include, at least, the following:

a) The Uphold Vaginal Support System;

b) The Pinnacle Pelvic Floor Repair Kit;

c) The Advantage Transvaginal Mid-Urethral Sling System;

d) The Advantage Fit System;

e) The Lynx Suprapubic Mid-Urethral Sling System;

f) The Obtryx Transobturator Mid-Urethral Sling System;

g) The Prefyx PPS System; and

h) The Solyx SIS System.

9. Boston Scientific designed, manufactured, packaged, labeled, marketed, sold, and distributed the following Pelvic Mesh Product, including that which was implanted in any

Plaintiff so indicated in a Short Form Complaint: Pinnacle Pelvic Floor Repair Kit, Uphold Vaginal Support System, Advantage Transvaginal Mid-Urethral Sling System, Advantage Fit System, Lynx Suprapubic Mid-Urethral Sling System, Obtryx Transobturator Mid-Urethral Sling System, Prefyx PPS System, Solyx SIS System, and/or Other.

Factual Background

10. On or about November 28, 2011, Margarita Santiago underwent Transobturator Tape Cystoscopy surgery where in an Obtryx Transobturator Mid-Urethral Sling was implanted for symptoms of urinary stress incontinence.

11. On or about May 22, 2019, while undergoing treatment for an anal fistula, it was determined that Mrs. Santiago had erosion of the Obtryx Transobturator Mid-Urethral Sling resulting in a vagina-cutaneous fistula that tracked to her left buttocks.

12. On or about June 6, 2019, Mrs. Santiago learned of the Obtryx Transobturator Mid-Urethral Sling product recall.

13. On August 13, 2019, Mrs. Santiago had surgery to remove the Obtryx Transobturator Mid-Urethral Sling, but all of the mesh could not be safely removed.

14. Defendant's Pelvic Mesh Product, including Obtryx Transobturator Mid-Urethral Sling System (herein after the "Product") contains monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in Plaintiff, Margarita Santiago is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Product. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendant's collagen Product cause hyper-inflammatory responses leading to problems including chronic pain and

fibrotic reaction. Defendant's collagen Product disintegrate after implantation in the female pelvis. The collagen Product cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal and/or human tissue. The collagen is harsh upon the female pelvic tissue. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non- anatomic condition in the pelvis leading to chronic pain and functional disabilities inserted in the female body according to the manufacturers' instructions, it creates a non- anatomic condition in the pelvis leading to chronic pain and functional disabilities

15. Surgical mesh Products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh Product that were designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of POP and SUI. Manufacturers, including Boston Scientific, began to modify the mesh used in hernia repair to be used as Product specifically intended to correct POP and/or SUI. Today, Boston Scientific sells pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Product manufactured by Defendant is considered Class II medical devices.

16. Defendant sought and obtained FDA clearance to market the Product under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted by Boston Scientific with regard to the Product.

17. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

18. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

19. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

20. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk.

21. The injuries of Mrs. Santiago, as will be more fully established in Discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

22. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh Product instead of other feasible alternatives did not outweigh the

associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

23. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

24. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (emphasis in original).

25. The FDA White Paper further stated that "these Product are associated with serious adverse events . . . compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

26. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

27. As is known to the Defendant, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh Product used to treat SUI in January of 2012.

28. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur . . . [and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh Product used for SUI."

29. Defendant did not, and have not, adequately studied the extent of the risks associated with the Product. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

30. Defendant(s) knew or should have known about the Product' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

31. Defendant knew or should have known that the Product unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

32. The scientific evidence shows that the material from which the Product are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Product, including the Mrs. Santiago.

33. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Mrs. Santiago.

34. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Product were unreasonably susceptible to degradation and fragmentation inside the body.

35. The Product were unreasonably susceptible to shrinkage and contraction inside the body. Defendant should have known of this serious risk and warned physicians and patients.

36. The Product were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

37. To this day, the Product have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing Product.

38. A woman who elects to have her SUI or POP surgically treated has several options. SUI can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials placed under the urethra to provide support.

POP can be corrected through abdominal or transvaginal surgery and using biologic, composite, or synthetic materials.

39. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of the Product, and advertised, promoted, marketed, sold and distributed the Product as safe medical devices when Defendant knew or should have known that the Product were not safe for their intended purposes, and that the Product would cause, and did cause, serious medical problems, and in some patients, including Mrs. Santiago, catastrophic injuries. Further, while some of the problems associated with the Product were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

40. Contrary to Defendant' representations and marketing to the medical community and to the patients themselves, the Product have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Mrs. Santiago, making them defective under the law.

41. The specific nature of the Product' defects includes, but is not limited to, the following:

a) The use of polypropylene and collagen in the Product and the immune reactions that result from such material, causing adverse reactions and injuries;

b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn

cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e) The propensity of the Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f) the inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g) The propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen Product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the Product, which are causally related to infection, as the mesh is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

42. The Product are also defective due to Defendant' failure to adequately warn or instruct Mrs. Santiago and/or her health care providers of subjects including, but not limited to, the following:

a) The Product' propensities to contract, retract, and/or shrink inside the body;

b) The Product' propensities for degradation, fragmentation and/or creep;

c) The Product' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The frequency and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Product;

f) The risk of chronic infections resulting from the Product;

g) The risk of permanent vaginal or pelvic scarring as a result of the Product

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i) The need for corrective or revision surgery to adjust or remove the Product;

j) The severity of complications that could arise as a result of implantation of the Product;

k) The hazards associated with the Product;

l) The Product' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

43. Defendant under reported and continues to underreport information about the propensity of the Product to fail and cause injury and complications and have made

unfounded representations regarding the efficacy and safety of the Product through various means and media.

44. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude, and frequency of the risks attendant to the Product.

45. Defendant failed to design and establish a safe, effective procedure for removal of the Product, or to determine if a safe, effective procedure for removal of the Product exists.

46. Feasible and suitable alternatives to the Product have existed at all times relevant that do not present the same frequency or severity of risks as do the Product.

47. The Product were at all times utilized and implanted in a manner foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

48. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of the Product and the aftercare of patients implanted with the Product.

49. The Product implanted in Mrs. Santiago was in the same or substantially similar condition as they were when they left Defendant' possession, and in the condition directed by and expected by Defendant.

50. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Product include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

51. In many cases, including Mrs. Santiago's case, women have been forced to undergo extensive medical treatment including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

52. The medical and scientific literature studying the effects of the Product, like that of the Obtryx Transobturator Mid-Urethral Sling System implanted in Mrs. Santiago, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Product.

53. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

54. At all relevant times herein, Defendant continued to promote the Product as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy or safety.

55. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Product, including the magnitude and frequency of these risks.

56. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Mrs. Santiago and the general public on notice of the dangers and adverse effects caused by implantation of the Product.

57. The Product as designed, manufactured, distributed, sold and/or supplied by Defendant were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant' knowledge of lack of safety.

58. As a result of having the Boston Scientific Obtryx Transobturator Mid-Urethral implanted in her, Mrs. Santiago has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

Causes of Action

COUNT I: NEGLIGENCE

59. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

60. Defendant had a duty to individuals, including Margarita Santiago, to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Product.

61. Defendant were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging, and selling the Product. Defendant breached its aforementioned duty by, among other things:

a) Failing to design the Product so as to avoid an unreasonable risk of harm to women in whom the Product were implanted, including Mrs. Santiago;

b) Failing to manufacture the Product so as to avoid an unreasonable risk of harm to women in whom the Product were implanted, including Mrs. Santiago;

c) Failing to use reasonable care in the testing of the Product so as to avoid an unreasonable risk of harm to women in whom the Product were implanted, including

Mrs. Santiago;

d) Failing to use reasonable care in inspecting the Product so as to avoid an unreasonable risk of harm to women in whom the Product were implanted, including Mrs. Santiago;

e) Failing to use reasonable care in the training and instruction to physicians for the safe use of the Product; Failing to use reasonable care in studying the Product to evaluate their safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

f) Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Product.

62. The reasons that Defendant's negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

a) The use of polypropylene and/or collagen material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d)

e) The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

f) The propensity of the Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

g) The inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

h) The propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

i) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

j) The propensity of the collagen Product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

k) The adverse tissue reactions caused by the collagen Product, which are causally related to infection, as the collagen is a foreign organic material from animals;

l) The harshness of collagen upon the female pelvic tissue; and

m) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

63. The reasons that Defendant's negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

a) The use of polypropylene and/or collagen material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e) The propensity of the Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f) The inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g) The propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen Product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the collagen Product, which are causally related to infection, as the collagen is a foreign organic material from animals;

k) The harshness of collagen upon the female pelvic tissue; and

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

64. Defendant also negligently failed to warn or instruct Mrs. Santiago and/or her health care providers of subjects including, but not limited to, the following:

a) The Product' propensities to contract, retract, and/or shrink inside the body;

b) The Product' propensities for degradation, fragmentation and/or creep;

c) The Product' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Product;

f) The risk of chronic infections resulting from the Product;

g) The risk of permanent vaginal or pelvic scarring as a result of the Product;

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i) The need for corrective or revision surgery to adjust or remove the Product;

j) The severity of complications that could arise as a result of implantation of the Product;

k) The hazards associated with the Product;

l) The Product' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r) Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

65. As a direct and proximate result of Defendant's negligence, Mrs. Santiago has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

66. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

67. The Product implanted in Mrs. Santiago were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Product' design defects include, but are not limited to:

a) The use of polypropylene and/or collagen material in the Product and the immune reaction that results from such material, causing adverse reactions and injuries;
b) The design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c) Biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause

surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d) The use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e) The propensity of the Product for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f) The inelasticity of the Product, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g) The propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h) The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i) The propensity of the collagen Product to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j) The adverse tissue reactions caused by the collagen Product, which are causally related to infection, as the collagen is a foreign organic material from animals and/or human cadavers;

k) The harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body;

l) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions, and

m) The use of polypropylene material in the Product and the failure to provide adequate directions for use (DFU) and training.

68. As a direct and proximate result of the Product' aforementioned defects as described herein, Mrs. Santiago has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future

medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

69. Defendant is strictly liable to Mrs. Santiago for designing, manufacturing, marketing, labeling, packaging, and selling a defective product(s).

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

70. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

71. The Product implanted in Mrs. Santiago were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendant's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to Mrs. Santiago.

72. As a direct and proximate result of the Product' aforementioned defects as described herein, Mrs. Santiago has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

73. Defendant is strictly liable to Mrs. Santiago for designing, manufacturing, marketing, labeling, packaging and selling defective Product.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

74. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

75. The Product implanted in Mrs. Santiago were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and

necessary warnings. Specifically, Defendant did not provide sufficient or adequate warnings regarding, among other subjects:

a) The Product' propensities to contract, retract, and/or shrink inside the body;

b) The Product' propensities for degradation, fragmentation, disintegration and/or creep;

c) The Product' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d) The rate and manner of mesh erosion or extrusion;

e) The risk of chronic inflammation resulting from the Product;

f) The risk of chronic infections resulting from the Product;

g) The risk of permanent vaginal or pelvic scarring as a result of the Product;

h) The risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

i) The need for corrective or revision surgery to adjust or remove the Product;

j) The severity of complications that could arise as a result of implantation of the Product;

k) The hazards associated with the Product;

l) The Product' defects described herein;

m) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product is no more effective than feasible available alternatives;

n) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product exposes patients to greater risk than feasible available alternatives;

o) Treatment of pelvic organ prolapse and stress urinary incontinence with the Product makes future surgical repair more difficult than feasible available alternatives;

p) Use of the Product puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q) Removal of the Product due to complications may involve multiple surgeries and

may significantly impair the patient's quality of life;

r) Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain; and

s) The nature, magnitude and frequency of complications that could arise as a result of implantation of the Product.

76. As a direct and proximate result of the Product' aforementioned defects as described herein, Mrs. Santiago has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

77. Defendant is strictly liable to Mrs. Santiago for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

COUNT V: BREACH OF EXPRESS WARRANTY

78. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

79. Defendant made assurances as described herein to the general public, hospitals and health care professionals that the Product were safe and reasonably fit for their intended purposes.

80. Mrs. Santiago and/or her healthcare provider chose the Product based upon Defendant' warranties and representations as described herein regarding the safety and fitness of the Product.

81. Mrs. Santiago, individually and/or by and through her physician, reasonably relied upon Defendant' express warranties and guarantees that the Product were safe, merchantable, and reasonably fit for their intended purposes.

82. Defendant breached these express warranties because the Product implanted in Mrs. Santiago were unreasonably dangerous and defective as described herein and not as Defendant(s) had represented.

83. Defendant' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective Product in the body of Mrs. Santiago, placing said Plaintiff's health and safety in jeopardy.

84. As a direct and proximate result of Defendant's breach of the aforementioned express warranties, Mrs. Santiago has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

85. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

86. Defendant impliedly warranted that the Product were merchantable and were fit for the ordinary purposes for which they were intended.

87. When the Product were implanted in Mrs. Santiago to treat her pelvic organ prolapse and/or stress urinary incontinence, the Product were being used for the ordinary purposes for which they were intended.

88. Mrs. Santiago, individually and/or by and through her physician, relied upon Defendant' implied warranties of merchantability in consenting to have the Product implanted in her.

89. Defendant breached these implied warranties of merchantability because the Product implanted in Mrs. Santiago were neither merchantable nor suited for their intended uses as warranted.

90. Defendant' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective Product in the body of Mrs. Santiago, placing said Plaintiff's health and safety in jeopardy.

91. As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Mrs. Santiago has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

COUNT VII: LOSS OF CONSORTIUM

92. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

93. As a direct and proximate result of the above-described injuries sustained by Mrs. Santiago, where applicable, her spouse named in the Short Form Complaint has suffered a loss of consortium, companionship, society, affection, services, and support.

COUNT VIII: DISCOVERY RULE, TOLLING, AND FRAUDULENT CONCEALMENT

94. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

95. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

96. Plaintiffs plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

97. Despite diligent investigation by Plaintiffs, including the female Plaintiff named in Plaintiff's Short-Form Complaint, into the cause of their injuries, including consultations with Plaintiffs' medical providers, the nature of Plaintiffs' injuries and damages, and their relationship to the Product was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims. Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

98. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant are estopped from asserting a statute of limitations defense due to Defendant' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and Plaintiffs' physicians of the true risks associated with the Product. As a result of Defendant' fraudulent concealment, Plaintiffs and Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant.

COUNT IX: PUNITIVE DAMAGES

99. All previous paragraphs of this Complaint are hereby incorporated by reference as if fully set forth herein.

100. Defendant sold their Product to the healthcare providers of Mrs. Santiago and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Product were reasonably safe for implantation in the female pelvic area.

101. Defendant sold the Product to Plaintiffs', including Mrs. Santiago, health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the Product can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by Mrs. Santiago and numerous other women.

102. Defendant ignored reports from patients and health care providers throughout the United States and elsewhere of the Product' failures to perform as intended, which lead to the severe and debilitating injuries suffered by Mrs. Santiago and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Product' designs or the processes by which the Product are manufactured as the cause of these injuries, Defendant(s) chose instead to continue to market and sell the Product as safe and effective.

103. Defendant knew the Product were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries, and treatments in an effort to cure the conditions proximately related to the use of the Product, as well as other severe and personal injuries which were permanent and lasting in nature.

104. Defendant withheld material information from the medical community and the public in general, including Mrs. Santiago, regarding the safety and efficacy of the Product.

105. Defendant knew and recklessly disregarded the fact that the Product caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or Product used to treat pelvic organ prolapse and stress urinary incontinence.

106. Defendant misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Product.

107. Notwithstanding the foregoing, Defendant continue to aggressively market the Product to consumers, without disclosing the true risks associated with the Product.

108. Defendant knew of the Product' defective and unreasonably dangerous nature but continued to mislead physicians and patients and to manufacture, market, distribute, and sell the Product so as to maximize sales and profits at the expense of the health and safety of the public, including Mrs. Santiago.

109. Defendant continues to conceal and/or fail to disclose to the public, including Mrs. Santiago, the serious complications associated with the use of the Product to ensure continued and increased sales of the Product.

110. Defendant' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, the Plaintiffs demand judgment against Defendant, and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well

as:

- Compensatory damages to Plaintiffs for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, emotional distress, mental anguish, physical disfigurement and impairment; health and medical care costs, together with pre- and post-judgment interest and costs as provided by law;
- Restitution and disgorgement of profits;
- Reasonable attorneys' fees;
- The costs of these proceedings;
- All ascertainable economic damages;
- Punitive damages; and
- Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

The Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Respectfully submitted,

MESSA & ASSOCIATES, P.C.

By: */s/ Alaina A. Gregorio*
Alaina A. Gregorio, Esquire
Attorney for Plaintiffs